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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,311	03/09/2006	Wilhelm Wurst	27234U	6257
34375	7590	04/01/2009	EXAMINER	
NATH & ASSOCIATES PLLC			SOROUSH, ALI	
112 South West Street				
Alexandria, VA 22314			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/571,311	WURST ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 March 2006.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-21,43 and 44 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06122006</u> .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Status of the Claims***

Claims 1-21 have been amended, claims 43 and 44 are newly added, and claims 22-42 have been cancelled by a preliminary amendment submitted on 03/09/2006. Therefore, claims 1-21 and 43 and 44 are currently pending examination for patentability.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-21, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. (US Patent Application 2004/0266869 A1, Published 12/30/2004).

***Applicant Claims***

Applicant claims a method for treating a respiratory disease in patient that is a child comprising administering a dose of a composition comprising ciclesonide in an amount from 20 to 200 $\mu$ g.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Montague et al. teach "pharmaceutical compositions based on anticholinergics drugs and ciclesonide ... and their use in the treatment of respiratory diseases." (See paragraph 0002). The pharmaceutical compositions are preferably administered by inhalation either as inhalable powders or aerosols. (See paragraph 0008). In a preferred embodiment the composition comprises tritropium bromide and ciclesonide in a doses of 1 to 10000 $\mu$ g; wherein there 10 $\mu$ g of tritropium bromide and 100 $\mu$ g of ciclesonide. (See paragraphs 0018 and 0019). If the composition is formed into an inhalable powder an excipient such as lactose monohydrate is preferably added to the composition. (See paragraphs 0024 and 0025). Alternatively the composition can be formed into a aerosol formulation the composition is dispersed in propellant gases such 1,1,1,2-tetrafluoroethane and 1,1,1,2,3,3-heptafluoropropane and mixtures thereof. (See paragraphs 0031-0033). The propellant composition can further include a co-solvent such as ethanol. (See paragraph 0034 and 0042). These compositions are particularly useful in treating COPD and asthma. (See paragraph 0013).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)***

Montague et al. does not anticipate wherein the patient is a child between the ages of 6 to 12 years. However, Montague et al. does make treatment of such patients obvious.

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the inhalation composition taught by Montague et al. in patients who are children between the ages of 6 to 12 years. One would have been motivated to do so because Montague et al. is silent as to the age of the patient receiving the composition, therefore one of ordinary skill in the art would expect that administration of Montague et al.'s composition to patients of any age would work equally well in treating COPD and asthma. Therefore, if one wanted to treat a child between the ages of 6 to 12 years suffering from COPD and/or asthma one would administer the composition of Montague et al. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush  
Patent Examiner  
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616